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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,053	10/07/2003	Roderico B. Estanislao	J&J-5081	6024
27777	7590	06/14/2007	EXAMINER	
PHILIP S. JOHNSON			GEMBEH, SHIRLEY V	
JOHNSON & JOHNSON			ART UNIT	PAPER NUMBER
ONE JOHNSON & JOHNSON PLAZA			1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/681,053	ESTANISLAO ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 February 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 17-20 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/27/05; 10/7/03; 2/13/04; 8/18/04
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of claims 1-16 in the reply filed on February 21, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant elected a non-woven material as the first and second water-insoluble material.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 1/27/05; 10/7/03; 2/13/04 and 8/18/04 have been received and acknowledged. The information disclosure statement filed 1/27/05, page 2 and 10/7/03, page 3 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because they don't have the year or pages as needed. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite first water insoluble substrate and second water insoluble substrate comprises at least 50 % or 10% by weight of the total weight of the substrate of a liquid carrier. It is not clear whether the 50% or the 10% is to the first or second water insoluble substrate.

Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "at least about" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack clarity as to whether "at least" (a lower limit) or about "(broadening limitation, both higher and lower) it is unclear what controls the metes and bounds of the phrase "at least about".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 9-16 are rejected under 35 U.S.C. 102(e) as being 35 U.S.C. 103(a) as being unpatentable over Rolf et al. US 2003/0152610 A1 in view of Muchin WO 00/62763 taken with Dolog US 6106818.

Rolf et al. teach, with regards to instant claims 1 and 15, a first water insoluble substrate having a different shape and a second water insoluble substrate having a different shape from the first water insoluble substrate (see diagram, fig's. 11 and 12) wherein the water-insoluble substrates are non-woven materials (see 0038-0039) of different shapes (see fig.s 11 and 12). The first shape is contour to fit around the forehead and the area around the mouth as shown in the figure.. The first water insoluble substrate comprises alcohol (see page 7, 0070) and glycolic acid, salicylic acid (see page 2, 0009) but fail to specifically teach them separate. With regards to claims 2 and 4, the teaching is obvious as all products do carry information of how to use.

The printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert of a kit and the product, composition, or article of manufacture of a kit or container.

See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of *In re Haller*, it is stated that: Whether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of Patentability is concerned . . . In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see *In re Venezia* 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, *In re Miller* 164 USPQ 46 (CCPA 1969) and *In re Gulak* (CAFC) 217 USPQ 401 relate to a mathematical device and to a measuring cup respectively as well as *In re Ngai*, 70 USPQ2d 1862 (CAFC 2004). In each of these cases, the printed matter is considered a patentable distinction because the function of the device

depends upon the printed matter itself, which is a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles or kits. The claimed articles of the kit remain fully functional absent the labeling or printed instructions for use.

Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, the claims are drawn to an old article or composition, which further comprises labeling instructions. The intended use, which is recited on the label or package of the insert, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, the old article or old composition of the kit can still be used by the skilled artisan for other purposes. Therefore the old article or composition which are

comprised with the claimed kit are unpatentable over the prior art, because they function equally effectively with or without the labeling, and accordingly no functional relationship exists between the instructions for use and the composition.

Thus the claims are addressed as being drawn to an article of manufacture comprising an old composition of a kit and a package insert, the instructions on the insert bearing no patentable weight with regard to double patenting, 102 and 103 rejections.

Regarding claims 3 and 16, the first water insoluble substrate is shaped for application on the forehead and the second water insoluble is substrate is shaped for application area proximate to the mouth (see fig's. 11-12). With regards to the discrete areas, the forehead is discrete from the mouth region, therefore the reference teaches the discrete areas.

Rolf et al. teach as to the instant claims 9-14, the active agent as a cosmetic agent to be glycolic and salicylic acid (see 0009) and C₂ – C₆ alcohol is propylene glycol (see 0146). Rolf also teaches the use of alcohols in the formulation (see 0070)

Muchin teaches a method for discrete application of the mask (see abstract) and also (see page 16, lines 22-25) wherein the active agent is an alcohol (see page 18-23).

Dulog et al. teach a fabric strip (here as a non-woven material) comprising alcohols having carbon atoms of C₂ – C₈ (see col. 10 lines 22-34).

Although, the non-woven face mask taught by Rolf et al. did not indicate the mask for the forehead to have a separate active agent from the mask for the lower half of the face, however, One of ordinary skill in the art would be motivated to combine the

above teachings and use different active agents for the forehead region comprising alcohol, because alcohol as taught by Dulos et al. to remove dead surface cells, dirt, oil or blackheads. The forehead is the most oily part of the face, it is located in the area known as the T-zone. The T-zone is where the oily glands are located as evident by Dermadoctor (see enclosed). Dermadoctor teaches or suggests that these areas of the face can be treated with different products for example the problematic area with stronger or oil absorbing product. Since these products have been used in a mask for the face "The motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Section MPEP 2144.07"

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
5/4/07

Ardin H Marschel 6/9/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER